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ABSTRACT

This document discusses the area of legal protection of intellectual property and owner control to its accessibility under the fourth exemption of the freedom of information act. (SL)

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Presentation of Norman J. Latker, Patent Counsel, DHEW
Before the Academy of Pharmaceutical Sciences
Atlanta, Georgia - November 19, 1975

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"THE PROTECTION OF INTELLECTUAL PROPERTY
UNDER THE FOURTH EXEMPTION OF THE FREEDOM
OF INFORMATION ACT"

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Since the departure of President Nixon, it appears to many that much of Congress's effort to restore itself, as it deems necessary, as an equal partner to the Executive and Judicial Branches in the "checks and balance" system has been directed to earlier involvement in the development of policy. Unfortunately, accompanying Congress's undeniable right to pursue such a course, a great many indiscriminate statements such as: "We've had it to the teeth with secrets" or "Anything the Executive refuses to make public amounts to lying to the American people" have served to create an atmosphere in which even the most obvious of the Executive's discretionary powers have become suspect. It is against this tidal wave of indignation and demands for openness that Federal Agencies must attempt to protect intellectual property placed in their hands by persons presuming that such property has nothing to do with the development of policy. Some such Agencies have already been swept away with this current passion while others are frustrated by the added administrative burden of protection which they view diverting their energy from primary assignments. Thus, some have moved to presumptions that no excuse for protection is available.

While I hold no particular brief for policy-making behind closed doors, I believe the fervor to promulgate "sunshine laws" to

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guarantee to all citizens the absolute right to access to all aspects of the Executive's business, subject to some narrow exceptions, underestimates or chooses to ignore the vastness of the Executive's interface with private industry, universities, and nonprofit organizations in the area of product and service regulation, and the seeding of research and development to solve social problems.

This interface as we all know requires submission of documentation within which are included disclosures of ideas, inventions, technical and clinical data, novel business and accounting methods, trade secrets, computer programs, etc. which represent the end result of a significant private investment and do now, or could in the future, confer the competitive advantages which justify the owners' past and continued investment and/or advocacy in delivering the service or item disclosed to the marketplace. This array of intellectual property is truly a substantial portion of the present and future building blocks and cornerstones of our free enterprise system.

Now, presuming that such submissions must continue in order to obtain the Government action sought, whether it be seed money to encourage initial research and development in areas of public concern or clearance of an item of service for public use, it follows that full "openness" could result in the total loss of the property value in such intellectual property which has not already been covered by patent protection. In other words, the entire area of legal protection of intellectual property available since the founding of this republic,

which exists due to the ability of the owner to control its access-
bility, will have no relevance when dealing with the Executive Branch.

(I would add inferentially at this point that as far as I can determine none of the "sunshine laws," including FOIA, distinguishes between the U.S. public and foreign interests. Thus, where a U.S. citizen can gain access, so can a foreign competitor or government.

When one of Congressman John E. Moss's constituents wrote to set forth his opinion that the present FOIA did not provide sufficient protection against premature disclosure of inventive ideas that were not yet patentable, the Congressman responded by indicating that:

"While I am sorry that the Act imposes a certain hardship on inventors, I feel strongly that the public has a right to know how Government funds are spent. As you realize, the FOIA only applies to Government information and if anyone is willing to accept Government funding for a project he must also be willing to accept the added responsibility of public scrutiny."

Of course, to construe, as I believe Congressman Moss had done, that a research proposal submitted for some type of funding support is government property is tantamount to a declaration that one forfeits all past and future personal proprietary rights and private equities in such dealings with the Government. I would note that the Congressman's position even denies to the Government the right to protect any

intellectual property within the research proposal in the interest of the public since the Government in turn must disclose to any third party under FOIA.

When one explores the present FOIA and the excessive burden it places on the Government administrator in protecting intellectual property against premature disclosure, it is clear that Congressman Moss's view had substantially prevailed in the drafting of the Act.

The FOIA generally requires disclosure of all Government records upon request. There are a number of exemptions to the required disclosure. Of these exemptions, we are primarily interested today in number 4 which appears to exempt "trade secrets and commercial or financial information which is privileged or confidential." The leading case on the fourth exemption, *National Parks and Conservation Association v. Morton*, 498 Fed. 765 (1974), D.C. Circuit Court, states that the fourth exemption applies if it could be shown that disclosure was either likely, first, to impair the Government's ability to obtain necessary information or second, to cause substantial harm to a competitive position of a person providing the information. The Court toughened the qualification in *Petkas v. Staats*, 501 F. 2d 887 (1974) by refusing to accept a government assurance of nondisclosure in a regulation requiring information where filing the information was conditioned on confidentiality. The Cost Accounting Standards Board regulation in the case required defense contractors to submit disclosure statements setting forth their accounting procedures, and the suit was to obtain public disclosure of the statements filed by Lockheed,

ITT, and General Motors. The court held that the Government assurance and the Corporations' respective filings conditioned on confidentiality were not determinative, and remanded the case for disposition in accordance with the test of the National Parks case noted above. Thus, a promise of confidentiality by the Government in and of itself may not prevent disclosure.

The Office of Legal Counsel of the Justice Department has advised that as a result of the above cases, government protection of intellectual property and its withholding under the fourth exemption under a FOIA suit is very unpredictable, at best.

Further, 18 U.S.C. 1905 does not appear to have any effect in a FOIA suit. This statute, if applicable, would impose criminal penalties on Government officials who disclose proprietary information in the possession of the Government. At best, then, it is a deterrent to unauthorized disclosure, but it only takes effect after the disclosure and the damage to the owner. 18 U.S.C. 1905 has been virtually ignored by the courts in FOIA suits because of a general exemption contained in the statute, "unless otherwise provided by law." Courts generally have interpreted the quoted passage as exempting disclosure under the FOIA. Section 1905's penalties, therefore, would not be applied to an official who disclosed proprietary information in response to a freedom of information suit.

Even though commercial concerns might with predictable difficulty meet the "substantial harm to a competitive position" test of the National Parks case, universities and nonprofit organizations wishing

to deny access to their research proposals appear to have little hope of meeting this test in light of *Washington Research Project v. Weinberger*. In that case, Washington Research Project sought access to a number of research proposals from different universities and nonprofit organizations in order to investigate the ethics of the experiments in question, most of which dealt with the treatment of hyperactive children. Washington Research supported its claim to access with indications that "it is essential for researchers to be held accountable, and the research process has to be something other than the closed society which it is now." The court indicated, in denying the use of the fourth exemption, that:

"It is clear enough that a noncommercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce. This is not to say that the scientist may not have a preference for or an interest in nondisclosure of this research design, only that it is not a trade or commercial interest . . ."

Now, if it is not already clear that the FOIA and present court interpretation is severely imbalanced toward prompting Federal Administrators to release intellectual property whether arguable within the fourth exemption or not, consider the Act's requirement

that the Federal Administrator provide a "yes" or "no" answer to a requester within 10 days of the request or be subject to severe personal financial penalties. The 10-day rule, as noted by Deputy Assistant Attorney General Mary Lawton, is "absolutely irrational. In some case you can't even get through the material required in 10 days."

Let me illustrate, in the case of a request for access to a research proposal. To say "no" basically requires that a Federal Administrator handling the request apply the National Parks test to the situation and provide a written prima facie case to the Department Public Information Officer recommending denial. If the information the Federal Administrator believes should be denied involves a disclosure of an idea, invention, trade secret, etc., a prior art search which indicates that such idea, invention, trade secret, etc., is in fact novel in comparison to the prior art must be conducted before a prima facie case could be made. If novelty cannot be shown it seems clear that the Government could not prevail in a suit to show that there will be "substantial harm to the owners' competitive position." I would ask inferentially at this point, how can a Federal Administrator, yet alone the owner, show that a computer program or a business method is novel compared to the prior art? Where would you look for the prior art? Should the owner be penalized

because the Administrator doesn't know how to make a case? In those few situations where "novel" information can be decisively identified and a denial considered justifiable, the Act further requires that the information to be denied be excised from the documents requested and the resulting "swiss cheese" document forwarded to the requester. Now multiply this procedure by the 200 research proposals Washington Research Projects requested shortly after prevailing in their first suit for access or the number of requests for similar information FDA receives.

Can it really be suggested that many Federal Agencies will travel the denial route in other than situations where the equities of the owner are immediately and dramatically apparent, when release merely requires a xerox copy to the requester with no threat of penalty under 18 U.S.C. 1905?

I note on the bright side that NIH has voluntarily adopted a policy of contacting our research investigators immediately after a request for release of research proposals to determine whether there is any intellectual property which he believes will be destroyed through premature disclosure. Of course, as already noted, the investigator's request to deny access is not determinative of the action which the Government will take under the National Parks case test, but it is certainly helpful in identifying those situations where access may be particularly damaging.

As suggested in the wake of the Washington Research Project case there has been a large surge of requests for release of research proposals. Although requesters need not identify the purpose of their requests, volunteered information in addition to their organizational identification seems to place requesters in two broad but identifiable categories;

- 1) Public interest groups pursuing the possibility that research investigators are in some way abusing the public interest in the course of their research, or
- 2) Commercial concerns and other research investigators wishing to capitalize on the work product disclosed.

The requester in the second category can ordinarily be identified as having an investment in the same field of research as the research proposal he is seeking. It has been ascertained through volunteered information from these requesters that they wish the information sought generally to either 1) determine the degree to which the investigator is moving the state of the art ahead or 2) use as a format for the requesters own grant or contract application.

At this time, it appears that public interest groups are requesting access to more research proposals than commercial concerns and research investigators. Notwithstanding the large number of research proposals requested by public interest groups, to my knowledge substantially all of the requests have

been made by only two groups. The large number of requests made by public interest groups seems easy enough to explain since the search for or the discovery of possible abuse appears to be the only way such groups can justify continued existence.

The requests from the commercial concerns and other research investigators cover a much smaller number of grants coming from a larger number of sources, since it appears that these requesters have a preconceived idea of exactly what they want.

Based on this preliminary and rather sketchy data, I am of the opinion that the primary beneficiaries of the Act gaining access to research proposals have been parties interested in enhancing their own financial or organizational positions at the expense of the work product of NIH-funded investigators, rather than the public on the basis of any identified evidence of redirection of policy development due to the action of public interest groups.

It is my understanding that the imbalance between the number of requests for intellectual property from commercial concerns and public interest groups is even more pronounced in the direction of commercial concerns at FDA.

At a September 24 meeting, the Inter-Assembly Council of the Assemblies of Scientists of NIH and NIMH voted to send every NIH and NIMH scientist and to Science magazine a notice of their concern, a part of which is as follows:

"The Inter-Assembly Council of the Assemblies of Scientists of the National Institutes of Health and National Institutes of Mental Health, while fully recognizing the legal right of scientists to make such a request, strongly urges NIH and NIMH Intramural scientists voluntarily continue to act according to past practice and not request copies of Grant Applications. We advocate this policy because we fear the effectiveness of the peer review system may be diminished and biomedical research impeded if applicants believe their Grant Applications will be widely circulated.

This recommendation is subject to revision should professional scientific societies adopt appropriate guidelines."

(I would suggest that when any group of scientists can agree to make a positive recommendation on anything, the situation has probably reached the point where other elements of society need also be concerned.)

Now the real issue in the controversy over release of research proposals is not whether the information therein will be released but when it will be released. It is perfectly clear that investigators are anxious to publish the results of their research for the scrutiny and critique of the entire profession when they believe it has moved to some reportable conclusion. The above statement by NIH and NIMH scientists clearly indicates that investigators in general, are not ready to relinquish the timing of publication to an unidentified third party.

The public interest groups insist that the timing of access should be in the hands of the public. The public in practice turns out to be self-designated surveillance groups whose opinions cannot be identified as representing any kind of public consensus and who are not subject to the "checks and balance" system.

In support of their position, public interest groups point to a very small number of research projects which they believe involve abuse of human subjects which they claim would not have been funded if they were involved in the clearance procedure. Now it is well known that NIH-funding procedure already includes means to devote special attention to the risk v. benefit problem when human subjects are to be involved. It seems entirely speculative that the addition of another echelon of review by public interest groups will enhance the quality of the existing review. In fact, the opposite may be the effect, since it seems that the groups now functioning outside the official surveillance procedure tend to equate the public interest to funding only those research projects with identified benefits and no risks. A number of investigators have noted that the atmosphere created by these groups is already resulting in replacing the remote possibility of any error of commission by many errors of omission. Dr. Dwight Harken of Boston, one of the Nation's pioneer heart surgeons, recently warned, "The fact that any failure of a device or procedure may be penalized has stifled innovation, restricted industry and

unfavorably affected the quality, distribution and cost of the delivery of health care."

Now when one compares the highly speculative benefits to be derived from permitting random access of research proposals to a few self-designated public interest groups against the measureable loss of intellectual property, investigator privacy, candor in decision making, effective evaluations and incentives for continued innovation, it is difficult to justify the present state of the law.

Although I and others in the Government believe this to be one of the more serious problems confronting our society, it has virtually had to beg for a forum. Both NASA and ERDA have brought this problem to Congress in the context of their research and as far as I can determine have made little progress toward resolution. The Association of American Medical Colleges has explained the problem to Congress in the context of NIH research in a much more comprehensive and articulate fashion than I have here, and have been equally unsuccessful. As far as I can determine, these organizations have been unable to separate to the satisfaction of Congress the issue of the need to protect most intellectual property in the hands of the Executive branch from Congress's preoccupation with opening the Executive's policy development process.

Admittedly there is an overlap, but not to the extent that the baby needs to be thrown out with the bath water.